KITAZATO®

EC DECLARATION OF CONFORMITY

Manufacturer: **Kitazato Corporation**
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E-mail : info@dibimed.com

Product: **Trade Name:** **Vitrification media and Thawing media with gentamicin**
Code number: **VT601 (Ref.91101) VT602 (Ref.91121)**
VT601N(Ref.91195) VT602N(Ref.91196)

Description: **Reagent for vitrifying and thawing oocytes and embryos for Assisted Reproductive Technologies procedures**

Classification: **Class III**
Rule 2, Rule3, Rule 13 and 17 according to Annex IX of the MDD

Conformity Assessment Route: **Annex II applied**

We herewith declare that the above-mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer and the notified body.

General applicable directives: Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC), as amended by Directive 2007/47/EC.

Standards: Harmonized Standards (published in the Official Journal of the European Communities) applicable to this product are as per the "LIST OF APPLIED STANDARDS".

Notified Body: BSI Group The Netherlands B.V. (ID #: 2797)
Say Building, John M. Keynesplein 9, 1066 EP Amsterdam,
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EC Certificate: Standard: EN ISO13485:2016
EC Certificate #: 563699 and
DesignExamination EC certificate #563702
Issued by: BSI PRODUCT SERVICES

Signature: Date: Sep 5, 2019

Name: Futoshi INOUE
Position: President and Representative Director, Kitazato Corporation